



Dora
Department of Regulatory Agencies

Division of Registrations
Rosemary McCool
Director

State Board of Pharmacy
Wendy Anderson
Program Director

John W. Hickenlooper
Governor

Barbara J. Kelley
Executive
Director

January 31, 2011

Royal Palm Compounding Pharmacy
Attn: Mark Rubin, RPH
117 S State Rd 7, Ste 201
West Palm Beach, FL 33414

**RE: Case #2011-2863 concerning Royal Palm Compounding Pharmacy, Inc., OSP
5852**

Dear Mr. Rubin:

Pursuant to the Board Policy 30-8, its staff has referred this case to the Office of Expedited Settlement based on a belief that the aforementioned pharmacy violated the Pharmaceuticals and Pharmacists Act and the Board Rules and Regulations. As part of this guidance, the Board indicated a willingness to consider settlement in lieu of a hearing and provided settlement parameters to that office.

A representative from the Office of Expedited Settlement will be contacting you in the near future.

Sincerely,

FOR THE COLORADO STATE BOARD OF PHARMACY

Susan S. Martin
Acting Program Director

cc: Office of Expedited Settlement
File

Policy Number: 30-8

Title: Prescription Drug Monitoring Program—Pharmacies that Fail to Submit Required Data to the Prescription Drug Monitoring Program

Date Issued: January 15, 2009

Revised: November 19, 2009

PURPOSE: To delegate to Board staff structured authority to administratively handle complaints which arise from pharmacies (both prescription drug outlets and nonresident prescription drug outlets) which fail to comply with the data submission requirements of the Prescription Drug Monitoring Program ("PDMP") on either a first time or repeated basis.

POLICY: Board staff shall follow the process set forth below when processing instances wherein either in-state or nonresident prescription drug outlets fail to maintain compliance with the reporting requirements of the PDMP.

A. Pharmacies with no record of prior complaints filed against them by the Board for failure to comply with the reporting requirements of the PDMP.

Pharmacies with no record of prior complaints filed against them by the Board for previous failure(s) to comply with the data submission requirements of the PDMP will be sent a warning letter directing them to come into compliance within 14 days. This shall be referred to as the "14-day letter." Disposition of matters involving a 14-day letter will be handled as follows:

1) **Compliance Following 14-Day Letter.** If the pharmacy comes into compliance and maintains compliance for two consecutive reporting periods following the date of the 14-day letter, no further action will be taken on the 14-day letter unless and until further instances of non-compliance occur.

2) **Failure to Comply Following 14-Day Letter.** If the pharmacy fails to come into compliance and to maintain compliance for two consecutive reporting periods following the date of the 14-day letter, a complaint will be issued against the pharmacy. The pharmacy shall have thirty days within which to respond to the complaint.

a) If the pharmacy comes into compliance and maintains compliance within two consecutive reporting periods following the due date of the complaint response, the complaint will be dismissed with a confidential letter of concern (LOC). Subsequent instances of failure to maintain complete compliance will be processed in accordance with subsection B below.

b) If the pharmacy fails to come into compliance and maintain compliance within two consecutive reporting periods following the thirty-day due date of the complaint response, the case will be processed in accordance with subsection B below.

3) **Compliance During One-Year Period Following 14-Day Letter.**

a) If the pharmacy has maintained complete compliance for a period of at least twelve months following the date of a 14-day letter and falls out of compliance more than twelve months after issuance of the 14-day letter, a new 14-day letter shall be issued and the pharmacy shall be given the opportunity to come into compliance pursuant to this subsection A.

b) If the pharmacy has failed to maintain complete compliance with the data submission requirements at any time during a twelve-month period from the date of a 14-day letter, a second

14-day letter will not be issued and a complaint will be initiated against the pharmacy. The case will be processed in accordance with subsection B below.

B. Pharmacies with one or more prior complaints filed against them by the Board for failure to comply with the reporting requirements of the PDMP.

In the event of any instances of non-compliance within five years following a past complaint for non-compliance, whether or not said complaint resulted in dismissal with an LOC, no 14-day letter will be issued and no new complaint will be initiated. Board staff shall open a new case and automatically refer it as a disciplinary action to the Office of Expedited Settlement for Expedited Settlement Processing ("ESP"). Settlement guidance will require one of the following:

Payment of a non-negotiable \$5,000 fine plus any surcharge as required by the Executive Director at relevant times pursuant to §24-34-108, C.R.S. and agreement to comply with the data submission requirements of the PDMP,

or relinquishment of registration.

Should the pharmacy decline settlement of the matter on the above terms, the case will be referred to the Office of the Attorney General with the same terms as guidance.

C. Pharmacies with one or more prior Disciplinary Actions for non-compliance.

In the event of any instances of non-compliance with the PDMP reporting requirements following any prior disciplinary actions against a pharmacy as described in subsection B above, no 14-day letter will be issued and no complaint will be initiated. Board staff will open a case and automatically refer it as a disciplinary action to ESP with the settlement guidance requiring one of the following:

Payment of a non-negotiable \$10,000 fine (\$5000 for failure to comply with prior disciplinary order plus \$5000 for failure to comply with data submission requirements of the PDMP) plus any surcharge as required by the Executive Director at relevant times pursuant to §24-34-108, C.R.S. and agreement to comply with the data submission requirements of the PDMP,

or relinquishment of registration.

Should the pharmacy decline settlement of the matter on the above terms, the case will be referred to the Office of the Attorney General with the same terms as guidance.



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March 4, 2011

Royal Palm Compounding Pharmacy
Attn: Mark Rubin, RPH
117 S State Road 7, Suite 201
West Palm Beach, FL 33414

RE: Stipulation and Final Agency Order
Case #2011-2863

IN THE MATTER OF THE DISCIPLINARY PROCEEDING REGARDING THE
NON-RESIDENT PRESCRIPTION DRUG OUTLET REGISTRATION OF ROYAL
PALM COMPOUNDING PHARMACY, REGISTRATION NO. OSP 5852,

Dear Mr. Rubin:

Enclosed you will find a copy of the fully executed Stipulation and Final Agency Order (Stip/FAO) in the above mentioned matter, which became effective March 3, 2011.

If you have any questions, or require additional information, please feel free to contact me at (303) 894-2989.

Respectfully,

FOR THE COLORADO STATE BOARD OF PHARMACY
PRESCRIPTION DRUG MONITORING PROGRAM

Tia Johnson
PDMP Administrator

Enclosure

cc: Lauri A. Rose, Settlement Specialist, Office of Expedited Settlement
File

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2011-002863

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF THE DISCIPLINARY PROCEEDING REGARDING THE NON-RESIDENT PRESCRIPTION DRUG OUTLET REGISTRATION OF ROYAL PALM COMPOUNDING PHARMACY, REGISTRATION NO. OSP 5852,

RESPONDENT PHARMACY.

IT IS HEREBY STIPULATED by and between the Colorado State Board of Pharmacy ("Board") and Royal Palm Compounding Pharmacy ("Respondent Pharmacy"), to resolve all matters pertaining to Board Case Number 2011-002863 as follows:

1. On December 4, 2009, Respondent Pharmacy became registered by the Board as a non-resident prescription drug outlet in the State of Colorado and was issued Registration No. OSP 5852 ("Colorado Registration").
2. The Board has jurisdiction over Respondent Pharmacy, its Colorado Registration, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the provisions of title 12, article 22, C.R.S. (2009), otherwise known as the Pharmaceuticals and Pharmacists Act.
3. Respondent Pharmacy's address of record with the Board and current location is 117 S. State Road 7, Suite 201, West Palm Beach, FL 33414.
4. Respondent Pharmacy admits these findings and hereby waives any further proof in this or any other proceeding before the Board regarding the following facts.
5. On August 20, 2010, Board staff initiated a Complaint against Respondent Pharmacy because it failed to comply with the data submission requirements of Colorado's Electronic Prescription Drug Monitoring Program ("PDMP") for the reporting period of August 1 through August 16, 2010.
6. Respondent Pharmacy subsequently failed to submit the required data to the PDMP reporting dispensing transactions of controlled substances in the State of Colorado for the reporting period of January 16 through January 25, 2011, and did not submit

a "zero" report indicating no dispensing transactions for said reporting period as required by Board rule.

7. Respondent Pharmacy admits that the conduct described above constitutes a violation of §§12-22-125(1)(c) and 12-22-708, C.R.S. and that such conduct provides grounds for disciplinary action against Respondent Pharmacy's Colorado Registration pursuant to Board Policy 30-8.

DISPOSITION

\$5,000.00 Fine with 10% Surcharge and Terms

8. **Fine with Surcharge.** Respondent Pharmacy accepts the following discipline: Pursuant to §12-22-125.2(5), C.R.S. Respondent Pharmacy shall pay a fine of **Five Thousand Dollars and No Cents (\$5,000.00)**. Respondent Pharmacy understands and acknowledges that, pursuant to §24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies shall impose an additional surcharge of 10% of this fine. Respondent Pharmacy shall therefore pay a total amount of **Five Thousand, Five Hundred Dollars and No Cents (\$5,500.00)**. The total amount shall be payable to the [State of Colorado] and shall be remitted in one lump sum to be included when Respondent Pharmacy submits this signed Final Agency Order to the Board.
9. **Compliance with PDMP.** At all times Respondent Pharmacy is registered with the Colorado State Board of Pharmacy, it shall comply with the data submission requirements of the PDMP. Respondent Pharmacy understands and acknowledges that future violations of PDMP reporting requirements, including failure to submit a "zero" report in the event of no dispensing transactions in Colorado during the relevant reporting period, shall lead to additional penalties pursuant to Board Policy 30-8.
10. **Advisements and Waivers.** Respondent Pharmacy enters into this Final Agency Order freely and voluntarily, after having had the opportunity to consult with its own legal counsel and/or choosing not to do so. Respondent Pharmacy acknowledges its understanding that it has the following rights:
 - a. To have a formal notice of hearing and charges served upon it;
 - b. To respond to said formal notice of charges;
 - c. To have a formal disciplinary hearing pursuant to §12-22-125, C.R.S.; and
 - d. To appeal this Board order.

Respondent Pharmacy freely **waives** these rights, and acknowledges that such waiver is made voluntarily in consideration for the Board's limiting the action taken against it to the sanctions imposed herein.

11. **Acknowledgments.** The undersigned authorized agent of Respondent Pharmacy has read this Final Agency Order in its entirety and acknowledges, after having had the opportunity to consult with its own legal counsel and/or choosing not to do so, that Respondent Pharmacy understands the legal consequences and agrees that none of the terms or conditions herein is unconscionable. Respondent Pharmacy is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent Pharmacy further acknowledges that it is not entering into this Final Agency Order under any duress.
12. **Violations.** Time is of the essence to this Final Agency Order. It is the responsibility of Respondent Pharmacy to take all appropriate steps to comply fully with this Final Agency Order. Respondent Pharmacy acknowledges and agrees that any violation of this Final Agency Order may be sanctioned as provided under §12-22-125.2(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of its registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent Pharmacy to comply with all terms and conditions of this Final Agency Order.
13. **Integration and Severability.** Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties in this case. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.
14. **Public Record.** Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.
15. **Effective Date.** This Final Agency Order shall become effective upon signature of a Board member or representative.

ACCEPTED AND AGREED BY

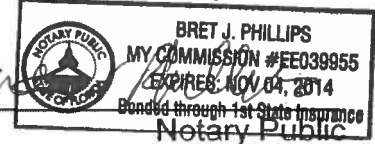


Authorized Agent of Respondent Pharmacy

Dated: 2-23-11

Subscribed and sworn to before me in the County of Palm Beach, State of Florida, this 23 day of February, 2011 by Bret Phillips, in his/her capacity as an authorized agent of Royal Palm Compounding Pharmacy.

My commission expires: 11/4/2014



FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

DONE AND EFFECTIVE THIS 3RD DAY OF March, 2011.

State Board of Pharmacy

BY: Wendy Anderson
~~Susan S. Martin~~ Wendy Anderson
~~Acting~~ Program Director

CERTIFICATE OF MAILING

This is to certify that I have duly mailed the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by depositing copies of same in the United States mail, postage prepaid, at Denver, Colorado this 9th day of February 2011, addressed as follows:

Royal Palm Compounding Pharmacy
Attn: Mark Rubin, RPH
117 S. State Road 7, Suite 201
West Palm Beach, FL 33414

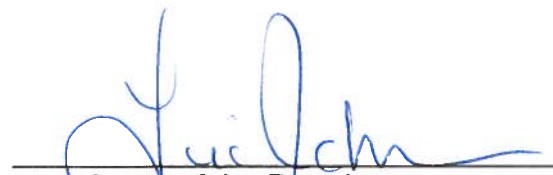


Lauri A. Rose

CERTIFICATE OF SERVICE

This is to certify that I have duly served the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by depositing copies of same in the United States mail, postage prepaid, at Denver, Colorado this 4th day of March 2011, addressed as follows:

Royal Palm Compounding Pharmacy
Attn: Mark Rubin, RPH
117 S. State Road 7, Suite 201
West Palm Beach, FL 33414



Agent of the Board